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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,281	06/22/2001	Partha S. Banerjee	18025-1013	6268

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EXAMINER
WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
1614	#16

DATE MAILED: 01/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/887,281	Banerjee et al.
Examiner	**Art Unit**
Kevin E. Weddington	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 22, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-61, 65-67, 71-73, 77-89, and 93-99* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *1, 4-61, 65-67, 71-73, 77-89, and 93-99* is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☒ Claim(s) *2 and 3* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *3 and 1*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-61, 65-67, 71-73, 77-89 and 93-99 are presented for examination.

Applicants' amendment and information disclosure statement filed August 22, 2002 and November 22, 2002 have been received and entered.

The petition filed July 22, 2002 was granted on October 8, 2002, therefore, claims 1-61, 65-67, 71-73, 77-89 and 93-99 will be examined.

Accordingly, the rejections made under 35 U.S.C. 102(e) and 35 U.S.C. 103 as set forth in the previous Office action at pates 3-5 are hereby withdrawn so that new rejections can be made.

Claim Objections

Claims 2 and 3 are objected to because the claims' limitations are not taught by the cited reference.

Claim Rejections - 35 U.S.C. § 112

Claims 71-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' specification does not contain any test results or any experimental data showing the instant composition will, in fact, prevent or ameliorate one or more

symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction especially in a mammal not presently at risk of or predisposed to developing such diseases or disorders.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 4-12, 18-21, 27-29, 35-38, 44-49, 54, 57-61, 77-79, 88, 89 and 94-99 are rejected under 35 U.S.C. 102(e) as being anticipated by Hochrainer et al. (B) .

Hochrainer et al. teach a formoterol active substance concentrate in the form of a solution or suspension. The solution or suspension containing formoterol can be stored therein a period from several months possibly up to several years (column 1, lines 55-66). The reference also teaches the solution or suspension can be used in inhalers for inhalation or nasal therapy (see the abstract). Note particularly column 1, lines 47-52 states the formoterol solution or suspension can be formulated into aerosol formulation which is converted by means of a nebulizer. Clearly, the cited reference teaches the applicants' instant pharmaceutical composition of claim 1 and the addition of a nebulizer. The reference also

teaches in column 2, lines 13-16, the polar fluids are preferred, particularly protic fluids (the same as applicants' polar solvents and protic solvents). Note particularly column 2, lines 57-64 for inorganic and organic salts that are used in the saline solutions (same as applicants' tonicity adjusting agents). Note particularly column 3, lines 42-45 teaches the pH of the formoterol of between 2.0 and 7.0, in which, the applicants' pH of about 2.0 to about 8.0 falls within the cited reference's pH range. Note particularly column 4, lines 55-68 and column 5, lines 1-6 teaches the buffer substances used in the solution (same as applicants' buffers). The reference also teaches the addition of other inhalatively active pharmaceutical substance such as anticholinergic and leukotriene antagonists (see column 8, claim 19), the same as applicants' additional ingredients of claims 77 and 94-99. Clearly, the cited reference anticipates the applicants' instant pharmaceutical composition, therefore, the instant pharmaceutical composition is unpatentable.

Claims 1, 4-12, 18-21, 27-29, 35-38, 44-49, 54, 57-61, 77-79, 88, 89 and 94-99 are not allowed.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-17, 22-26, 30-34, 39-43, 50-53, 55, 56, 58, 65-67, 71-73, 80-87, 92-93 and 97-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. (B).

Hochrainer et al. was discussed above supra for its pharmaceutical composition comprising formoterol.

The instant invention differs from the cited reference in that the cited reference does not teach the applicants' preferred concentrate for the buffer. However, to determine a concentration having optimum effectiveness is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine optimum concentrations to get the maximum effect of the buffer.

The instant invention differs from the cited reference in that the cited reference does not teach the concentration range of formoterol. However, to determine a concentration having optimum effectiveness is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine optimum concentrations to get the maximum effect of formoterol.

The instant invention differs from the cited reference in that the cited reference does not teach concentration range of the anticholinergic agent. However, to determine a

concentration having optimum effectiveness is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine optimum concentration to get the maximum effect of the anticholinergic agent.

Claims 13-17, 22-26, 30-34, 39-43, 50-53, 55, 56, 58, 65-67, 71-73, 80-87, 92, 93 and 97-99 are not allowed.

The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner K. Weddington whose telephone number is (703) 308-1235.

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington

January 21, 2003